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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,845	02/04/2004	Andrew G.C. Frazier	MVMDINC.019A	9741

20995 7590 03/08/2007  
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EXAMINER

POUS, NATALIE R

ART UNIT PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/08/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/08/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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# Office Action Summary

Application No.

10/771,845

Applicant(s)

FRAZIER ET AL.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/5/05, 1/21/05, 9/7/04, 8/9/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of claims 1-17 in the reply filed on 1/4/07 is acknowledged.

### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 recites the limitation "the catheter" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4, 7, 9, 10, 11, 13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Koike et al. (US 6221092).

Regarding Claim 1, Koike teaches a method of closing a patent foramen ovale having a septum primum and a septum secundum (D), comprising: providing a closure device having a proximal end (1), a distal end (2), a proximal segment (1), an intermediate segment (3) and a distal segment (2), the proximal and intermediate

segments defining a first clip-shaped portion and the intermediate and distal segments defining a second clip-shaped portion (fig. 6); and deploying the closure device within the patent foramen ovale such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate portion lying in a channel between the septum primum and the septum secundum (fig. 3); wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together (Column 2, proximate lines 43-54).

Regarding Claim 4, Koike teaches the method of claim 1, wherein the first clip-shaped portion and second clip-shaped portions are made of wire (Column 3, proximate lines 61-67).

Regarding Claim 7, Koike teaches the method of claim 1, wherein deploying the closure device comprises releasing the closure device from a detachment element (62) provided on the device.

Regarding Claim 9, Koike teaches the method of claim 1, wherein the device self-expands to its deployment configuration (figs. 4-6)).

Regarding Claim 10, Koike teaches a method of closing a patent foramen ovale having a septum primum and a septum secundum, comprising: providing a closure device having a proximal end (1) and a distal end (2) and having a generally elongate configuration (fig. 4) and a clip configuration (fig. 6), wherein when the device is in its elongate configuration the proximal and distal ends are pulled away from each other and when the device is in its clip configuration the device has generally an S-shape (fig.

6), releasably attaching the device relative to a delivery device; delivering the closure device to the patent foramen ovale with the delivery device, the closure device being held relative to the delivery device in its elongate configuration; and deploying the closure device in the patent foramen ovale, wherein the device when deployed includes a first clip-shaped portion positioned around the septum secundum and a second clip-shaped portion positioned around the septum primum (Column 5, proximate lines 19-60).

Regarding Claim 11, Koike teaches the method of claim 10, wherein the closure device includes a detachment element (111) at its proximal end, and the device is delivered using a core wire (62) that releasably engages the detachment element.

Regarding Claim 13, Koike teaches the method of claim 10, wherein the device is delivered by positioning the catheter between the septum primum and septum secundum (fig. 6).

Regarding Claim 15, Koike teaches the method of claim 10, wherein the device self-expands to its deployment configuration (figs. 4-6).

Regarding Claim 16, Koike teaches the method of claim 10, wherein the device includes a plurality of eyelets (111), and the device (62) is releasably attached to a delivery device by engaging a core through at least some of the eyelets.

Claims 1-5, 7, 9, 10, 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Peavey et al. (US 2003/0225421).

Regarding Claim 1, Peavey teaches a method of closing a patent foramen ovale having a septum primum (14) and a septum secundum (16), comprising: providing a closure device having a proximal end (26), a distal end (40), a proximal segment (22), an intermediate segment (36, 38) and a distal segment (44), the proximal and intermediate segments defining a first clip-shaped portion and the intermediate and distal segments defining a second clip-shaped portion (fig. 3a); and deploying the closure device within the patent foramen ovale such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate portion lying in a channel between the septum primum and the septum secundum (fig. 3b); wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together (par. 42).

Regarding Claim 2, Peavey teaches the method of claim 1, wherein the intermediate (38) and distal (44) segments of the closure device when deployed are positioned along surfaces of the septum primum (14) and the proximal (22) and intermediate segments (38) of the closure device when deployed are positioned along surfaces of the septum secundum (16, fig. 3b).

Regarding Claim 3, Peavey teaches the method of claim 1, wherein the first clip-shaped portion and second clip-shaped portions are integrally formed (fig. 3b).

Regarding Claim 4, Peavey teaches the method of claim 1, wherein the first clip-shaped portion and second clip-shaped portions are made of wire (par. 32, proximate lines 1-2).

Regarding Claim 5, Peavey teaches the method of claim 1, wherein the first clip-shaped portion and second clip-shaped portions when the device is deployed forms generally an S-shape (fig. 3a).

Regarding Claim 7, Peavey teaches the method of claim 1, wherein deploying the closure device comprises releasing the closure device from a detachment element (27) provided on the device.

Regarding Claim 9, Peavey teaches the method of claim 1, wherein the device self-expands to its deployment configuration (par. 33).

Regarding Claim 10, Peavey teaches a method of closing a patent foramen ovale having a septum primum and a septum secundum, comprising: providing a closure device having a proximal end (26) and a distal end (40) and having a generally elongate configuration (par. 42, lines 2-3) and a clip configuration (fig. 3a), wherein when the device is in its elongate configuration the proximal and distal ends are pulled away from each other and when the device is in its clip configuration the device has generally an S-shape (fig. 3a), releasably attaching the device relative to a delivery device; delivering the closure device to the patent foramen ovale with the delivery device, the closure device being held relative to the delivery device in its elongate configuration; and deploying the closure device in the patent foramen ovale, wherein the device when deployed includes a first clip-shaped portion positioned around the septum secundum and a second clip-shaped portion positioned around the septum primum (par. 42).

Regarding Claim 13, Peavey teaches the method of claim 10, wherein the device is delivered by positioning the catheter between the septum primum and septum secundum (par. 42).

Regarding Claim 15, Peavey teaches the method of claim 10, wherein the device self-expands to its deployment configuration (par. 33).

Claims 1 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Ryan et al. (US 2003/0191495).

Regarding Claim 1, Ryan teaches a method of closing a patent foramen ovale having a septum primum and a septum secundum, comprising: providing a closure device having a proximal end (142), a distal end (144), a proximal segment (142), an intermediate segment (26) and a distal segment (144), the proximal and intermediate segments defining a first clip-shaped portion and the intermediate and distal segments defining a second clip-shaped portion (fig. 4); and deploying the closure device within the patent foramen ovale such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate portion lying in a channel between the septum primum and the septum secundum (fig. 4); wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together.

Regarding Claim 6, Ryan teaches the method of claim 1, wherein each clip-shaped portion is formed from two adjacent loops (142, 144) connected by a connecting portion (fig. 17).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peavey in view of Neuss (US 6355052).

Peavey teaches all limitations of preceding dependent claim 10 as previously described, and further teaches wherein the device includes a detachment element (27), but fails to teach wherein the device is delivered using a core wire which releasably engages the detachment element. Neuss teaches a closure device wherein the device includes a detachment element (25) at its proximal end, and the device is delivered using a core wire (27) that releasably engages the detachment element in order to provide exact positioning or repositioning of the device before deployment.

Claims 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike in view of Wahr et al. (US 2002/0183787).

Koike teaches all limitations of preceding dependent claims 1 and 10, but fails to teach locking the device in position after deployment. Wahr teaches a device for closing a PFO wherein the device is locked in position after deployment in order to selectively engage the device with the PFO. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Koike with a locking mechanism in order to selectively engage the device with the PFO.

Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Koike in view of Huebsch et al. (US 6312446). Koike teaches all limitations of preceding dependent claim 10, but fails to teach, wherein the device is held in its elongate configuration distal to a deployment catheter. Huebsch teaches a method for closing a septal defect, wherein the device is held in its elongate configuration distal to a deployment catheter (fig. 5b) in order to ensure correct placement of the device before deployment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Koike as taught by Huebsch in order to ensure correct placement of the device before deployment.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP  
3/1/07

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

3/2/07